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EXAMINER	
WALSH, S	
ART UNIT	**PAPER NUMBER**
1812	18

18N2/0309

WENDY M LEE
GENENTECH INC
460 POINT SAN BRUNO BOULEVARD
SOUTH SAN FRANCISCO CA 94080-4990

DATE MAILED: 03/09/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~_____ days~~ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☑ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 3, 5, 7, 22 and 26 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☑ Claims 3, 5, 7, 22 and 26 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☑ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1812.

2. The preliminary amendment has been entered.

3. The disclosure is objected to because of the following informalities: the specification is not in compliance with 37 CFR 1.52(b) because the top margins of the specification pages are less than 3/4"(2 cm); the first line on each of the following pages has been damaged by hole punching, and can be restored by amendment: pages 3, 5, 7, 8, 10, 12, 16, 19, 20 and 22. See MPEP 608.01. Appropriate correction is required.

4. The drawings are objected to for the reasons on the attached Form 948. It appears that this form should have been attached to Paper No. 7, the Office Action in 08/048,346 that was mailed 10/4/93. Correction is required.

The Brief Description of the Drawings should be amended to refer to Panel A and Panel B in Figure 1. Applicants are reminded that when a formal Figure 13 is prepared, if the sequence requires separate sheets, the separate sheets should be

labeled as subfigures: Fig. 13A, Fig. 13B, etc., and the Brief Description of the Drawings should be amended accordingly.

5. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 3, 5, 7, 22 and 26 are again rejected under 35 U.S.C. § 103 as being unpatentable over Yamamoto et al(AJ) or Coussens et al(AL) each in view of Weber et al, Dull et al. or Dower et al. Yamamoto et al. disclose the complete amino acid and nucleotide sequences for the HER2, or c-erbB-2, tyrosine kinase

receptor, see Figure 2, page 231, show the extracellular domain, transmembrane domain and intracellular domain, see Figure 3, page 232, and discuss the similarity of the extracellular domain to that of EGF receptor, page 233, ¶2. Yamamoto et al. teach that a 2.3 kb transcript encoding only the extracellular domain is synthesized in MKN-7 cells, that the expression product from this transcript should be secreted, that this expectation of secretion is similar to what is observed with the similar secreted, truncated form of EGF receptor, and indicate that the secreted, truncated form of HER2 may be associated with the transformed phenotype, paragraph bridging pages 233-234. Coussens et al. disclose the complete nucleotide and amino acid sequences for the HER2, or c-erbB-2, tyrosine kinase receptor, see Figure 3, page 1135, and teach its similarity to other receptors, paragraph bridging pages 1133-1134, and see Figure 4, page 1136. The references do not teach isolated polypeptide comprising secreted HER2 extracellular domain terminating about 8 amino acids upstream of the transmembrane portion. Each of Weber et al., Dull et al., or Dower et al. teaches the advantages of obtaining soluble extracellular domains of receptor proteins. Weber et al. teach recombinant soluble forms of the IL-2 receptor lacking the transmembrane and cytoplasmic domains, see abstract and page 56, and that soluble receptors have practical applications in drug screening assays and receptor affinity purification of ligands.

Dower et al. similarly teach recombinant IL-1 receptor lacking the transmembrane and intracellular domains have been deleted, col. 14, lines 2-26, and a composition comprising receptor and adjuvant for making antibodies, Example 7. Dull et al. teach hybrid receptors comprising a receptor ligand binding domain and a reporter polypeptide, which would be immunogenic in animals because it has an immune epitope, and assays for identifying biologically active ligands or their antagonists or agonists, see entire document, especially cols. 1-2. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to make and use HER2 extracellular domain because either of Yamamoto et al. or Coussens et al. identifies the structure of the extracellular domain, because Yamamoto et al. suggest that it would be produced by the cells they identify, and because the secondary references teach various reasons why extracellular receptor domains are useful. In choosing where to terminate the extracellular domain on expression, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to terminate the sequence about eight residues upstream of the transmembrane domain because Yamamoto et al. teach that is the approximate end of the second cysteine cluster, see Figure 3, page 232, which would reasonably be expected to stabilize the conformation.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stephen Walsh whose telephone number is (703) 308-2957. The Examiner can normally be reached on Monday-Friday from 8:00AM to 4:00PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Garnette D. Draper, can be reached on (703) 308-4232.

Papers related to this application may be submitted to Group 1800 in Crystal Mall 1 by facsimile transmission, in conformity with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The FAX phone number for Art Unit 1812 is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephen Walsh

Stephen Walsh, Ph.D.
Primary Examiner
Group 1800

SW
March 6, 1995